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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,867	01/21/2000	Michael J. Imperiale	11203-002001	5039

20985 7590 07/01/2002

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	15

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/488,867	Applicant(s) IMPERIALE, MICHAEL J.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 21 January 2000 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Final Rejection

Claims 1-42 are pending examination.

The addition of claims 40-42, amendment of claims 1-10, 12-13, 15-20, 23-25, 27-35; and applicant's traversal filed on 4/2/02 are acknowledged and considered.

Drawings

NOTE: In the next response, please submit a response to the PTO 498 because a PTO 498 was filed with the non-final rejection dated 11/27/01 and the applicant has not submitted proposed corrections to the drawings. If the reply to the Final Rejection does not have a response to the 498, the response will be considered non-responsive. See 37 CFR 1.85(a).

Claim Objections

The objection for claim 33 is moot because of the amendment to claim 33. However, the objection to claim 9 remains for the following reason:

Claim 9 remains objected to because of the following informalities: The wording of the phrase on page 8 should read, "fiber gene, hexon gene, or combination thereof."

In addition, in view of the amendment to claims 1, 17, 18. 19, 20, 27, 31, 32, 33, and addition of new claims 40 and 41. Claims are objected to because of the following informalities: The wording of the phrase should read, "fiber gene, hexon gene, or combination thereof."

Claim 15 is objected to as being dependent upon a rejected base claim (claim 1), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Appropriate correction is required.

The rejection under 112 written description for claims 1-39 are withdrawn in view of the amendment to the claims. However, in view of the amended and the addition of new claims a new rejection under 112 written description follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 16-42 as best understood, are readable on a genus of a polypeptide having activity of a 52/55 kDa trans-acting protein and/or a nucleic acid sequence encoding a polypeptide having activity of a 52/55 kDa trans-acting protein, wherein the genus of polypeptides and/or polynucleotide sequences are not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates production of a genus of a nucleic acid sequence encoding a polypeptide having the activity of a first adenovirus serotype 52/55 kDa trans-acting protein and lacking the ability of a second adenovirus serotype 52/55 kDa trans-acting protein. The as-filed specification provides sufficient description of a mutant adenovirus (H5pm8001) incapable of expressing the 52/55kDa protein. The adenovirus comprises a nucleic acid

sequence, which is mutated and is lacking the activity of an adenovirus serotype 5, 52/55 kDa trans-acting protein.

However, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the a genus of a polypeptide having activity of a 52/55 kDa trans-acting protein and/or a nucleic acid sequence encoding a polypeptide having activity of a 52/55 kDa trans-acting protein as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of a nucleic acid sequence encoding a polypeptide having 52/55 kDa activity, and/or final products of a vector system that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient to support the present claimed invention directed to a genus of a polypeptide having activity of a 52/55 kDa trans-acting protein and/or a nucleic acid sequence encoding a polypeptide having activity of a 52/55 kDa trans-acting protein if the claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming an unspecified a genus of a polypeptide having activity of a 52/55 kDa trans-acting protein and/or a nucleic acid sequence encoding a polypeptide having activity of a 52/55 kDa trans-acting protein, and/or a genus of a vector system that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description

requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of a polypeptide having activity of a 52/55 kDa trans-acting protein and/or a nucleic acid sequence encoding a polypeptide having activity of a 52/55 kDa trans-acting protein and/or vector systems that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant traverses the rejection for claims 1-39 under 112 written description because the pending claims have been amended to distinguish the nucleic acid of the present invention. See page 13.

Applicant's traversal is acknowledged and is not applicable to the new rejection set forth under 112 written description.

Claims 38-39 remain rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. A heterologous nucleic acid operably linked to a transcriptional sequence (e.g. promoter) is considered critical or essential to the practice of the

invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claimed invention encompasses "a vector system comprising a heterologous nucleic acid sequence operably linked to a promoter" (pages 26-28). It appears from the specification that the active step for expressing a heterologous nucleic acid is by operably linking a transcriptional control sequence. In view of *In re Mayhew*, the claim is not enabled by the disclosure.

Applicant's traversal is not found persuasive because it is not applicable to the rejection under In re Mayhew.

Claims 1-14 and 16-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) A vector system for selectively packaging a replication defective adenovirus nucleic acid sequence in an adenovirus capsid based on adenovirus serotype, comprising a first nucleic sequence comprising 5' and 3' adenovirus ITRs, an adenovirus serotype cis-acting packaging signal, a heterologous nucleic acid; and a helper virus comprising: 5' and 3' adenovirus ITRs, a second nucleic acid sequence encoding an adenovirus serotype cis-acting packaging sequence and a DNA sequence encoding a functional 52/55 kDa trans-acting protein; wherein the adenovirus serotype of the first nucleic acid sequence is different then adenovirus serotype in the second nucleic acid sequence; 2) A vector system for selectively packaging a replication defective adenovirus nucleic acid sequence in an adenovirus capsid based on adenovirus serotype, comprising a first nucleic sequence comprising 5' and 3' adenovirus ITRs, an adenovirus serotype cis-acting packaging signal sequence, a heterologous nucleic acid, and a DNA sequence encoding a mutated adenovirus serotype 52/55 kDa trans-acting protein that is not functional; and a cell, which is genetically modified by transfecting the

cell with a second nucleic acid sequence encoding a functional adenovirus serotype 52/55 kDa trans-acting protein, wherein the adenovirus serotype in the first nucleic acid sequence is different then adenovirus serotype in the second nucleic acid sequence and does not reasonably provide enablement for the rest of the disclosed embodiment; 3) The vector system of either 1 or 2, wherein the replication defective adenovirus comprises a defective E1 gene, E2 gene, E3 gene, E4 gene, E4 promoter, penton gene, fiber gene, hexon gene, or combination thereof; 4) A composition comprising the vector of 1; and does not reasonably provide enablement for other claimed embodiments embraced by the breadth of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possession of a genus of a polypeptide having activity of a 52/55 kDa trans-acting protein and/or a nucleic acid sequence encoding a polypeptide having activity of a 52/55 kDa trans-acting protein), particularly in view of the reasons set forth above, one skilled in the art would not have known how to use and make the claimed invention so that it would operate as intended, e.g. function in a vector system for selectively packaging replication defective adenovirus nucleic acid sequence in an adenovirus capsid.

The claimed invention is a vector system for selectively packaging a replication defective adenovirus nucleic acid sequence in an adenovirus capsid without packaging the helper virus and avoiding the possibility of producing replication competent adenoviral vectors. The field of the invention lies in using a polypeptide sequence having the activity of 52/55 kDa trans-acting protein and gene therapy.

The state of the art in 1998 for predicting tertiary structure (biological activity) from a polypeptide sequence, as exemplified by Chiu et al., *Folding and Design*, Vol. 3, pg. 223-228, May 1998, displays major consideration for predicting a protein tertiary structure involve issues that include:

> Predicting the three-dimensional conformation of a correctly folded protein can be divided into two distinct steps: the construction of a fitness function to evaluate the various conformations: and the search through various possible conformations for the "best" prediction most likely to represent the native state. Neither part of this problem has proven particularly tractable. The development of a general method for the prediction of protein tertiary structure based on the protein sequence remains, unfortunately, one of the great-unsolved problems of computational biophysics (pg. 223).

The as-filed specification discusses that the invention features a novel adenoviral vector system that can produce replicant defective adenoviral vectors while avoiding the production of replication competent adenoviral vectors by using different 52/55 kDa trans-acting proteins. The specification provides working examples encompassing the production of vector system (pages 33-36).

Furthermore, with respect to the claimed invention encompassing making and/or using a polypeptide having the activity of a 52/55 kDa trans-acting protein, the as-filed specification provides description of a 52/55 kDa trans-acting protein from different adenoviruses. However, the prior art and the as-filed specification lack sufficient guidance for a representative number of species of a polypeptide having the activity of a 52/55 kDa trans-acting protein that would reasonably extrapolate to the genus for one skilled in the art to make and/or use the genus of polypeptides for the full scope of the claimed invention. The essential feature of the claimed invention is the requirement of staring material (e.g. a polypeptide having the activity of a 52/55

kDa trans-acting protein. It is not apparent how to make any other polypeptide having 52/55 kDa activity other than 52/55 kDa trans-acting protein in adenoviruses due to the reasons set forth above. More specifically as to the lack of reasonable extrapolation from the biological functional of 52/55 kKa to that of any other polypeptide having the activity of 52/55 kDa trans-acting protein, it would take one skilled in art an undue amount of experimentation to make and/or use the full scope of the claimed invention. Especially with lack of sufficient guidance required for predicting any protein tertiary structure based on a protein structure. At the time the application was filed, predicting any protein tertiary structure based on a protein structure was considered to be unpredictable due to significant problems in several areas (see Chui et al.).

In addition with respect to claims 36-39, which encompass a pharmaceutical composition comprising the vector system of claim 1 and a method of delivering a heterologous nucleic acid to a cell comprising transforming a cell using the pharmaceutical composition. The claims read on an in vivo and/or in vitro therapeutic method of gene therapy. The disclosure and prior art do not provide sufficient guidance for one skilled in the art to use the pharmaceutical composition in any therapeutic method of gene therapy. The state of the art for gene therapy as exemplified by Rubanyi (Molecular Aspect of Medicine, Vol. 22, 2001, pages 113-142) teaches that:

> The most promising areas for gene therapy today are hemophilias and cardiovascular diseases. This is based on the relative ease of access of blood vessels for gene therapy, and also because existing gene delivery technologies may be sufficient to achieve effective therapeutic benefits for some of these indication (transient expression in some but not all affected cells is required to achieve a therapeutic effect at a relatively low does of vector) (abstract). For other diseases (including cancer) further development in gene delivery vectors and gene expression systems will be required. It is important to note, that

> there will not be a universal vector and each clinical indication may require a specific set of technical hurdles to overcome. These will include modification of viral vectors, engineering of non-viral vectors by mimicking the beneficial properties of viruses, cell-based gene delivery technologies, and development of innovative gene expression regulation systems (abstract).

Furthermore, Anderson et al., *Nature*, Vol. 392, pp. 25-30, April 1998, displays major consideration for any gene transfer or any DNA therapy protocol involve issues that include:

1) The type of vector and amount of DNA constructs to be administered,
2) The route and time course of administration, the sites of administration, and successful uptake of the claimed DNA at the target site;
3) The trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA product, the amount and stability of the protein produced, and
4) What amount of the expressed proteins considered to be therapeutically effective for a DNA therapy method (Anderson, *Nature*, Vol. 392, pp. 25-30, April 1998).

In addition, all of these issues differ dramatically based on the specific vector used, the route of administration, the animal being treated, therapeutically effective amount of the DNA, and the disease being treated.

Anderson also teaches that gene therapy is a powerful new technology that still requires several years before it will make a noticeable impact on the treatment of disease, and that several major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered (pp. 25-30).

Anderson further teaches that the reason for the low efficiency of gene transfer and expression in human patients is that we still lack the basis understanding of how vectors should be constructed what regulatory sequences are appropriated for which cell types (page 30, column 1, last paragraph). Furthermore, Verma, *Nature*, Vol. 389, pages 239-242, 1997, indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target

tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2).

The specification teaches a method for making replication defective adenovirus vector system (example 1). In addition, the as-filed specification lists several heterologous nucleic acids that could be used in a method of gene therapy. Also, the disclosure contemplated that the exact amount and concentration of virus and the amount of formulation in a given dose and the route of delivery can be determines by a clinician. Also, the disclosure contemplates transfecting germ or somatic cells in a mammal. The as-filed specification does not provide any working examples using the vector system for expressing any heterologous nucleic acid or what amount of heterologous nucleic acid is required to observed a therapeutic effect in a method of gene therapy. Furthermore, one skilled in the art of gene therapy would understand that adenovirus vectors rarely integrate into the host chromosome and is mostly suitable for transient expression. In addition with respect to route of administration (e.g. systemically, regionally, locally), "adenovirus vectors have been aimed at controlling local-regional diseases (e.g. cystic fibrosis or primary tumors)." See Imperial et al, Molecular biology of adenovirus gene therapy vectors. In. A. Cid-Arregui and A Garcia Carranca (eds.): "Viral Vectors: Basic Science and Gene Therapy," Eaton, Natick, MA, pp. 119-128. In these therapies the virus is delivered directly to the affected tissue, and the spread of virus to surrounding non-diseased tissue is limited. This is an important issue, because it has been shown that systemic

delivery of adenovirus can cause severe hepatotoxicity." See Imperiale, page 123.

Imperiale further states:

> Obtaining persistence of a heterologous nucleic acid may be a more difficult task. Adenovirus vectors can stimulate an immune response in the host or the transgene itself could be immunogenic. Thus, clearance of cells transfected with the adenovirus vector can result in the loss of the therapeutic gene expression. While this might not be a problem in the treatment of diseases in which one wishes to kill the cell, such as cancer, it is a problem in other instances when long-term expression is desired. See page 124.

In view of the prior art, the specification fails to provide sufficient guidance for any method of gene therapy.

Therefore, in view of the In re Wands Factors, claims 36-39 are not enabled by the specification, which does not provide sufficient guidance for one skilled in the art to use the vector system for any therapeutic method of gene therapy. One skilled in the art of gene therapy would interpret that the breadth of the claim encompasses a therapeutic level of expressing a heterologous nucleic acid in a cell. However, in view of the breadth of the claims, the specification does not provide sufficient guidance for one skilled in the art to use the vector system described above for therapeutically treating any disease (e.g. hemophilia, cancer, etc.) or defects that require precise gene regulation (e.g. diabetes). In view of the doubts expressed above by Anderson, Rubanyi, and Verma, the specification and prior art at the time the application was filed, the as-filed specification fails to provide sufficient guidance for one skilled in the art to reasonably extrapolate from making a replication defective adenovirus vector system to using the vector system in any method of gene therapy for delivering a heterologous nucleic acid to an in vitro cell and/or in vivo cell to therapeutically treat a genetic defect in any mammal. Furthermore, Rubanyi teaches:

> That some applications of gene therapy require no precise gene expression regulation because they involve proteins with large therapeutic windows (such as adenosine deaminase, CFTR, and coagulation factors VIII and IX). These applications, however, represent only a small part of the clinical potential for gene therapy. Most therapeutic proteins have limited therapeutic windows, both in terms of their level and their duration of action for effective protein delivery, control over the level and duration of gene expression (page 124).

Thus in view of the In Re Wands Factors, listed above, the quantity of experimentation required to determine the delivery route of a nucleic and what amount of nucleic is required to treat a genetic disorder that requires precise regulation of gene expression, the direction provided by the as-filed specification encompasses using gene therapy to treat any disease, the working examples encompass making a vector system, the state of the gene therapy was considered predictable when treating a genetic disorder that does not require precise gene expression, the relative skill of those in the art, and the breadth of the claims; the as-filed specification fails to provide sufficient guidance for how to correct any disease in any mammal. Furthermore, the as-filed specification lacks sufficient guidance for the whole genus of pharmaceutical compositions, which would require an undue amount of experimentation for one skilled in the to determine which pharmaceutical composition displays a therapeutic effect in a mammal in view of the art of record displaying that a universal vector does not exist for use in treating any disease or disorder.

Furthermore, with respect to claim 42, which reads on a vector system for selectively packaging a replication defective nucleic acid sequence in a virus capsid, the claim reads on any virus capsid and the as-filed specification only provides

sufficient guidance for one skilled in the art to make and/or use an adenoviral capsid because the breadth of the claim encompasses using any viral capsid and the specification lacks sufficient guidance for one skilled in the art to reasonably extrapolate from an adenoviral capsid to any other viral capsid. There is a numerous number of viral capsid in the art (e.g. AAV, HIV, Ebola, HSV, etc.) and the state of the art is absent for how to make and/or use any viral capsid for producing a vector system for selectively packaging a replication defective nucleic acid sequence other than an adenoviral capsid. Therefore, in view of the lack of guidance provided by the as-filed specification, the claimed invention is only enabled for making and/or using an adenoviral capsid.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable 1-4, listed above. Given that gene therapy wherein any carrier is employed to correct a disease or a medical condition in any mammal was unpredictable at the time the application was filed, and given the lack of sufficient guidance as to a gene therapy effect produced by the gene delivery vector cited in the claims or modifying adenovirus early or late gene(s), one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicants' disclosure and the unpredictability of gene therapy and modifying adenovirus early and late genes. Furthermore, the as-filed specification lacks sufficient guidance for the whole genus of pharmaceutical compositions, which would require an undue amount of experimentation for one

skilled in the to determine which pharmaceutical composition would display a therapeutic effect in a mammal.

Applicant traverses the rejection for claims 1-20, 27-33, 35-39 under 112 enablement because the pending claims have been amended to distinguish the nucleic acid of the present invention. See page 13.

Applicant's traversal is acknowledged and to the extent that the traversal is applicable to the new or old rejections, the traversal is not found persuasive for the following reasons: the traversal and/or the as-filed specification and/or the art of record lack sufficient guidance and/or factual evidence for one skilled in the art to make and/or use any polypeptide having the activity of 52/55 kDa trans-acting protein other than the 52/55 kDa from adenoviruses. In addition, the traversal and/or the as-filed specification do not provide sufficient and/or factual evidence for one skilled in the art to make and/or use a pharmaceutical composition because the as-filed specification lacks sufficient guidance for the whole genus of pharmaceutical compositions, which would require an undue amount of experimentation for one skilled in the to determine which pharmaceutical composition would display a therapeutic effect in a mammal and the unpredictability of gene therapy provided by the art of record.

The rejection under 112 second for claims 1-20, 27-33, and 35-39 is withdrawn because of the amendment to the claims.

No claim is in condition for allowance because of the reasons set forth above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635
6/28/02

DAVE T. NGUYEN
PRIMARY EXAMINER